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Effect of shelf versus accelerated aging of UHMWPE on delamination in knee wear simulation

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Abstract

Severe delamination wear, fracture and subsurface embrittlement caused by oxidation have been observed in gamma-irradiation-sterilized UHMWPE tibial components of knee prostheses. In the present study, gamma-air-sterilized, shelf aged UHMWPE disks delaminated and fractured within a few hours of testing in a ball-on-flat knee wear simulator. In an earlier study, gamma-air-sterilized disks subjected to accelerated aging showed only moderate adhesive wear in 8 week wear tests. The fact that established methods of accelerated aging did not cause clinically relevant damage should be noted because these methods are commonly used in the evaluation of new types of UHMWPE developed for clinical use.

Keywords: Shelf aging; Accelerated aging; UHMWPE; Delamination wear

1. Introduction

Hundreds of thousands of ultra-high molecular weight polyethylene (UHMWPE) tibial and acetabular inserts are implanted every year in orthopaedic operations of the knee and the hip joints [1]. Modern arthroplasty is largely built on this ductile, reliable and forgiving biomaterial, and it appears likely that future arthroplasty will rely on it for decades to come. The long-term stability, durability and safety of UHMWPE are undoubtedly of very high clinical significance. Since UHMWPE was introduced in orthopaedics half a century ago, an intense research activity has gradually grown around the topic, and many different types of UHMWPE have been developed, clinically used and followed. It was learned from the large-scale clinical problem posed by severe delamination wear and fracture of UHMWPE tibial inserts in the 1990's that oxidation due to sterilization by gamma irradiation is one of the key issues to be controlled [2]. Presently, a substantial research effort is focused on the oxidative stability. In the improvement of wear resistance, crosslinking by irradiation has been a major field of research since the late 1990's. As phenomena of polyolefin chemistry, crosslinking and oxidation are closely related. New types of UHMWPE are continually being developed, and their propensity to oxidation must be evaluated. Various methods of accelerated (artificial) aging have been used in laboratory studies of oxidation, mechanical properties and wear. If the method results in an underestimation of real oxidation, conclusions may be too optimistic [3].

Sterilization of UHMWPE components by gamma irradiation in air has been found to lead to oxidation during shelf storage and in vivo [2,4]. Oxidation, which is a consequence of the generation of free radicals during irradiation, is one form of polymer degradation and is detrimental for strength [5]. Because of the oxidation problem, gamma irradiation and storage in an inert gas such as nitrogen has been brought into use, and it is a common practice not to implant components with more than 5 years of shelf age. Other ways of attempting to reduce or avoid oxidation include various heat treatments to eliminate free radicals, addition of a vitamin E antioxidant, and sterilization by ethylene oxide or gas plasma [1]. Gamma irradiation, especially in doses much above that needed for sterilization (25 to 40 kGy) is beneficial for wear properties because of crosslinking, but the post-irradiation heat treatments tend to impair mechanical properties.

Delamination wear has been observed in UHMWPE tibial components of prosthetic knees removed from patients [2,4]. This detrimental wear mechanism caused by oxidation manifests itself by the detachment of large flakes resulting in an quarry-like damage (Fig. 1). If the edge breaks or is worn off, and especially if the entire tibial component breaks, the biomechanical function of the prosthetic knee is compromised. In cross-sections of aged UHMWPE components, subsurface embrittlement caused by oxidation, the so-called white band, is clearly visible [2,4].

Two commonly used methods of accelerated aging are ASTM F2003-02(2008) [6], according to which the UHMWPE specimens are kept for two weeks in pure oxygen of 0.5 MPa pressure at 70 ºC, and air convection oven aging. The wear performance of gamma-air-sterilized UHMWPE (GUR 1050) disks that had been subjected to accelerated aging by the above methods, was studied with a knee wear simulator of the ball-on-flat (BOF) type [7]. Delamination did not occur in 5 million cycle wear tests. Instead, moderate adhesive wear took place resulting in a burnished appearance, similar to that of non-irradiated disks. There was no white band in the cross-sections. In the second BOF study [8], gamma-air-sterilization of the disks just prior to the tests was found to reduce the wear rate by 17 per cent compared with non-irradiated disks ($p = 0.005$), apparently due to crosslinking.

Numerous studies have been published on the oxidation and mechanical properties of shelf aged, in vivo aged and artificially aged UHMWPE [1]. Wear studies, however, in which a direct comparison is made between the effects of real and artificial aging using validated wear test methods, are lacking. The difficulty of producing delamination after artificial aging has been observed by other researchers as well [9]. The hypotheses of the present study were that (a) the absence of the clinically relevant wear mechanism, delamination, in knee wear simulation of gamma-air-sterilized UHMWPE components subjected to accelerated aging is due to the absence of severe subsurface oxidative embrittlement, the white band, and (b) for the correct simulation of the principal knee wear mechanisms of UHMWPE, the type of multidirectional motion is of primary importance.

2. Materials and methods

The three-axis, five-station, ball-on-flat (BOF) knee wear simulator (Fig. 2) has been described in detail elsewhere [7,8]. Briefly, the motion, implemented electromechanically with crank mechanisms, consisted of three sinusoidal components, flexion-extension (FE, ±21.2º) of the CoCr ball, and anterior-posterior translation (APT, ±5 mm) and internal-external rotation (IER, ±5º) of the UHMWPE disk. Any single-axis, and any combination of two-axis motion could be applied as well. All 7 different relative motions (FE+APT+IER, FE+APT, FE+IER, APT+IER, FE only, APT only, and IER only) were included in the present study. With the established three-axis motion the principal slide track on the disk was a figure of eight with a height of 10 mm and crossing angle of 10º. Relative to the disk, the direction of sliding was opposite to the direction of translation of the ball, due to FE. The ratio of rolling to sliding was 0.5. Due to APT, the contact stress field moved cyclically relative to the disk which is considered essential for the conditions of fatigue wear. The cycle frequency was 1.07 Hz. The load was vertical, and set to be static 2.0 kN. The polyethylene disk had a diameter of 40 mm and thickness of either 10 mm or 5 mm. For the attachment, the disk had a 3 mm thick and 3 mm wide flange on which the disk was clamped to the flat base plate made from stainless steel. The ball of 54 mm diameter was polished CoCr (ISO 5832-4, ASTM F75). The acrylic lubricant chamber contained the lubricant, HyClone Alpha Calf serum SH30212.03, diluted 1:1 with distilled water. The push-pull-rod of the APT mechanism consisted of a load cell and two spherical bearings, so the force needed for APT could be continuously measured. Alternatively, one end of the rod was fixed to the machine frame instead of the FE shaft. In this case, the coefficient of friction was calculated so that the force needed to prevent APT was divided by the load. Wear was quantified by weighing with a Mettler AT261 DeltaRange balance having a resolution of 0.01 mg. The wear factor was calculated by dividing the gravimetric wear by the density, load and sliding distance. The wear mark area was determined graphically from a photograph and the depth by measuring the lowest thickness of the disk with a caliper.

The UHMWPE (GUR 1050, Perplas IMP 2000) disks were machined from ram extruded round bar of 50 mm diameter. The shelf aged disks had been packed, gamma sterilized (25 to 35 kGy) and stored in air until the present tests were run on the average 12 years after the irradiation. Besides gamma sterilization, the disks were not treated in any other way. The reference disks, made from the same round bar as the shelf aged disks, were not irradiated. The disk number in Table 1 indicates the test sequence.

3. Results

The gamma-air-sterilized, shelf-aged UHMWPE components were damaged within a few hours of testing in the BOF simulator. The wear factor ranged from 6.4×10^{-5} mm^3/Nm to 1.6×10^{-3} mm^3/Nm (Table 1). Flakes of polyethylene floating on the lubricant (Fig. 3) and the up and down motion of the loading system were indications of damage, which was of the delamination type (Fig. 4). The disks of 5mm thickness fractured after 30 and 60 min only. A subsurface white band was visible as in a cross-section chip (Fig. 5). The centerline of the band was located at a depth of 0.7 to 0.8 mm from the surface. The width of the band was 0.7 to 0.8 mm and the material that formed the band was brittle. The surface layer of 0.3 to 0.4 mm thickness and the core were more ductile. To check the load carrying capability of the core, tests 14, 15 and 16 were continued after the early damage. During the continuation of the tests the wear settled, having reached a depth of 1.1 to 2.5 mm. In test 15 with three measurement points, the wear rate was 1540 mg/10^6 cycles (R^2 = 0.9956). The new bearing surface formed by the core was uneven (Fig. 6) which is in agreement with the rugged edge of the white band.

The non-irradiated disks showed a burnished wear mark with three-axis motion (Fig. 7a), and wear factors were of the order of 1×10^{-6} mm^3/Nm. In the absence of FE the worn surface was more undulated (Fig. 7b). The absence of APT resulted in a wear factor of 2.2×10^{-8} to 3.3×10^{-8} mm^3/Nm. In the absence of IER, and of both FE and IER, the wear was still measurable, whereas with FE only and IER only, wear could not be detected by weighing.

With non-irradiated disks and three-axis motion, the coefficient of friction, as evaluated at the neutral position of the ball (FE = 0º, APT = 0 mm, IER = +5º or -5º), was 0.035 ± 0.005. As the contact moved from the neutral position towards the extremes (APT = +5 mm or -5 mm), the force needed for the APT increased to a typical peak value of ±200 N. This was mainly caused by the elastic and plastic deformation of the disk. In tests with delamination damage, the peak value of the APT force increased to ±500 N, but steadily without sudden changes. The increase was due to the formation of the wear pit that was deepened and consequently the force needed to 'climb the slope' increased. From this signal, the effect of sliding friction was difficult to distinguish. Without APT, the coefficient of friction against an uneven bottom of wear pit (disk 15 after wear tests) was 0.010, lower than that (0.015) against an undamaged disk.

4. Discussion

The BOF knee wear simulator successfully produced the clinically relevant delamination wear mechanism and fractures with gamma-air-sterilized, shelf-aged UHMWPE GUR 1050 disks showing a subsurface white band. The wear factor was high, ranging from 6.4×10^{-5} to 1.6×10^{-3} mm^3/Nm. These findings markedly differ from earlier test results after accelerated aging using otherwise similar materials and methods [7,8]. Accelerated aging of gamma-air-sterilized UHMWPE disks according to ASTM F2003-02 (pure oxygen, 0.5 MPa pressure, 70 ºC, 14 days) did not lead to delamination in 5 million cycle (8 week) wear tests, nor was any white band present. The wear factors of disks of 10 mm and 5 mm thickness were 0.77×10^{-6} mm^3/Nm and 1.27×10^{-6} mm^3/Nm, respectively [7]. Accelerated aging in an air convection oven (14 days at 100 ºC) did not produce a subsurface white band, either, but the surface was brittle [7]. As a consequence, the wear factor at half a million cycles was 5.0×10^{-6} mm^3/Nm, but after one million cycles the wear factor settled to a value of 0.30×10^{-6} mm^3/Nm, close to that of non-irradiated disk, 0.33×10^{-6} mm^3/Nm [7]. The burnished wear marks (Fig. 8) were similar to those seen in non-irradiated disks. In a shelf aged tibial component only, delamination occurred (Fig. 9).

Gamma-sterilized conventional UHMWPE tibial components of prosthetic knees subjected to accelerated aging in an air convection oven (35 days at 80 ºC) were tested in a knee joint simulator [10]. Delamination was reported but delamination damage as severe as that observed in the present study was absent. Highly demanding test conditions resulted in more severe delamination [11]. In other knee simulator studies with gamma-sterilized UHMWPE, the ASTM F2003-02 method led to delamination in demanding test conditions [12,13], but the damage was mild compared with the present results. In a reciprocating ball-on-flat study [14], delamination was observed; the method of accelerated aging was 4, 6, or 8 days in ogygen at 0.5 MPa and 80 ºC, which differs from the standard method. In another reciprocating ball-on-flat study that used the standard method, delamination was reported [15], but a white band was not shown.

The type of delamination and the white band seen in the present study have been observed in tibial components removed from patients (Fig. 1) [2,4]. Delamination is a problem characteristic of prosthetic knees because the contact stresses are high and the contact stress field moves cyclically back and forth relative to the UHMWPE component. In delamination, a subsurface fracture, parallel to the surface, takes place. The subsurface weakening caused by oxidation contributes to this phenomenon [5]. When the fracture has grown to a critical size, a large flake is detached. The mechanism results in the formation of a macroscopic ‘quarry’ which affects the biomechanical function of the knee, especially if the edge is worn off or breaks.

It appears that the ASTM F2003-02 method [6] does not produce the most severe form of oxidative damage, the subsurface embrittlement visible as a white band, that compromises the tribological and biomechanical function, in a gamma-air-sterilized UHMWPE (GUR 1050) component. After gamma irradiation in air, UHMWPE is in a most vulnerable state regarding oxidation. The fact that the white band is not produced could be disregarded by stating that the white band is merely a phenomenon of the 1990s, the reasons for which are now known, and corrective measures taken. On the other hand, if the method cannot produce the type of oxidation that prompted its development, one can ask how realistic is the type of oxidation it produces with new types of UHMWPE [3]. For instance, when the effects of antioxidants such as vitamin E on the wear properties of UHMWPE are being evaluated [16], it should be taken into account that accelerated aging using contemporary methods may not cause oxidative damage as severe as that caused by shelf and in vivo aging. Therefore, further development of accelerated aging methods should be considered.

Presently many manufacturers have replaced gamma sterilization in air by irradiation and storage in an inert gas, and the recommended maximum storage time of UHMWPE components is 5 years, the time they are guaranteed to be sterile. There is however no universal ban on gamma sterilization in air or on implanting components after more than 5 years of shelf age. By strict criteria, the present components were tested as over-aged but the damage produced still closely resembled that seen in retrieved components. Oxidation may take place in vivo but at a slower rate than in air, because of the low oxygen concentration of the synovial fluid [17]. In vivo oxidation and subsurface embrittlement have been observed in components that have been packed and irradiated in an inert gas [18]. The leakage of the barrier package is likely to result in considerable oxidation if the storage time exceeds 5 years [1].

The anterior-posterior translation (APT) proved to be of the utmost importance in the knee wear simulation. APT alone was sufficient for the early delamination damage (test 29), which is understandable considering the structural weakness of the shelf aged components. In the absence of APT however, the wear of the shelf aged disk no. 19 was only 1.7 mg after 516 000 cycles, i.e., 134 hours of running. Without APT the ball did not penetrate the surface layer, but the disk was able to bear the 2 kN load and the combination of FE and IER. The diameter of the contact was only 10 mm in this test, so the maximum contact pressure could be as high as 40 MPa. When APT was returned, the wear was 224 mg in one hour. This dramatic increase of the wear factor by five orders of magnitude showed as a shift from a mild adhesive wear mechanism to a macroscopic destruction of the surface, the formation of a pit with an area of 330 mm^2 and depth of 1.1 mm. The high shear force caused by the APT of the elastic-plastic depression by the femoral ball quickly broke the surface layer.

It appears possible that a polyethylene component with subsurface embrittlement can work well for quite a while if there is no substantial cyclic translation of the contact point. This indicates that the wear rate can be low for many years. Only after the surface layer has been worn through, the wear rate increases steeply as the brittle layer is quickly penetrated. After that, the situation is to some extent stabilized as the less brittle core is reached. As tests with disks 14 to 16 were continued after the start of delamination, the disks were found to remain functional despite the high APT force caused by the wear pit. The wear rate however was relatively high. In test 15 with three wear measurement points the wear rate after the early damage was 1.5 $g/10^6$ cycles, corresponding to a wear factor of 4.0×10^{-5} mm^3/Nm.

Delaminating components produce a large amount of UHMWPE debris which is likely to have adverse biological consequences, such as osteolysis [19], although a large percentage of the volume of the debris may be macroscopic (Fig. 3) and therefore less harmful. The brittle flakes may be gradually ground to smaller, biologically more active particles. Secondly, the wear pit will increase the anterior-posterior forces as the new shape of the tibial bearing surface is more conforming. A biomechanical problem arises if the edge is broken or worn off. The biomechanical stability is compromised in the most serious way if the entire tibial component fractures, which was the case with the thin disks 5 and 6. With two disks of 10 mm thickness (nos. 1 and 19) fractures occurred as well, and the edge was broken in tests 28 to 30. The contact between the metallic femoral component and the metallic tibial baseplate is bound to have adverse clinical consequences, such as metallosis.

With three-axis motion, the burnished wear marks of the non-irradiated disks were similar to those seen in disks machined from the same round bar and tested 12 years earlier for 3.3 million cycles [8]. Moderate adhesive wear macroscopically manifested as burnishing results from multidirectional sliding and protein-containing lubricant and is considered to be the principal wear mechanism in well-functioning prosthetic joints with conventional UHMWPE [20]. The wear factors were not far from those measured 12 years earlier for non-irradiated disks, $3.9 \pm 0.4 \times 10^{-7}$ mm^3/Nm ($n = 5$). Without FE, the wear mark was less polished due to non-typical undulations (Fig. 7). With APT, the wear factor was 40 times higher than without it (test 21). In the absence of IER, or FE and IER (test 23), the wear factor was low and of the same order of magnitude as in test 21. In the absence of both APT and IER (test 22), or FE and APT (second part of test 24), the wear was so low that it could not be quantified by weighing. Of the possible different relative motions, the three-axis motion appeared to be the most recommendable for wear test devices. The wear rates measured for non-irradiated disks were close to those obtained with a knee simulator for EtO sterilized UHMWPE tibial inserts [21]. Abrasion of femoral components is known to take place in vivo [22], but abrasive wear was outside the scope of the present study.

5. Conclusions

The three-axis ball-on-flat knee wear simulator reproduced the clinically relevant delamination wear and fracture with gamma-air-sterilized, shelf aged UHMWPE disks showing subsurface white band, with remarkable similarity to retrieved, clinically delaminated tibial components. The delamination wear markedly differed from earlier BOF test results with similar disks that were gamma-air-sterilized, but subjected to accelerated aging procedures, ASTM F2003-02 and air convection oven, which did not cause subsurface embrittlement and did not lead to delamination in 8 week wear tests. When new types of UHMWPE are being evaluated it should be taken into account that the use of established accelerated aging methods may result in an underestimation of the oxidative damage with respect to delamination wear. With the combination of flexion-extension, anterior-posterior translation and internal-external rotation, a realistic knee wear simulation can be produced with a simplified test geometry, ball-on-flat, for UHMWPEs with highly varying wear resistance.

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Conflict of interest

None.

Table 1. Ball-on-flat knee wear tests with shelf-aged and reference UHMWPE disks.
In cases of continued test, amount of wear and wear factor for each part of test are presented.

Disk no.	Thick-ness (mm)	Gamma-irradiated	Shelf aging (months)	Test duration (min)	Number of cycles	Wear (mg)	Wear factor (mm^3/Nm)	Wear mark Area (mm^2)	Wear mark Depth (mm)	Special test condition
1	10	4/2000	140	120	7 700	115.0	3.9E-04	330	1.0	
2	10	3/2001	139	180	11 600	91.0	2.1E-04	440	1.0	
3	10	3/2001	139	180	11 600	28.4	6.4E-05	410	0.6	
4	10	3/2001	139	180	11 600	112.0	2.5E-04	570	1.3	
5	5	4/2000	151	30	1 900	115.9	1.6E-03	340	0.9	
6	5	4/2000	151	60	3 900	97.0	6.6E-04	320	0.9	
7	10	3/2001	141	330	21 200	156.4	1.9E-04	640	1.3	
8	10	3/2001	141	154	9 900	140.2	3.7E-04	420	0.9	
9	10	3/2001	141	161	10 300	94.2	2.4E-04	380	0.6	
10	10	3/2001	142	134	8 600	45.9	1.4E-04	500	0.3	
11	10	3/2001	142	148	9 500	44.4	1.2E-04	530	0.8	
12	10	3/2001	142	128	8 200	116.7	3.7E-04	350	0.8	
13	10	3/2001	142	360	23 100	89.3	1.0E-04	660	0.8	
14	10	3/2001	142	120	7 700	76.2	2.6E-04			
				120	7 700	123.4	4.2E-04	580	1.1	
15	10	3/2001	142	185	11 900	31.4	6.9E-05			
				6 200	395 000	649.9	4.3E-05			
				2 340	150 000	175.8	3.1E-05	1 090	2.5	
16	10	3/2001	142	240	15 400	63.6	1.1E-04			
				240	15 400	85.3	1.5E-04	750	1.2	
17	10	non-irr.	–	8 620	553 000	18.0	8.7E-07	230	0.4	
				8 570	550 000	22.1	1.1E-06	270	0.6	
18	10	non-irr.	–	8 630	554 000	19.6	9.5E-07	230	0.4	
19	10	3/2001	143	8 040	516 000	1.7	4.4E-08	80	0.2	no APT
				60	3 900	223.9	1.5E-03	390	1.1	
20	10	non-irr.	–	8 410	540 000	10.8	5.4E-07	210	0.3	
21	10	non-irr.	–	8 520	547 000	0.9	2.2E-08	105	0.2	no APT
				8 570	550 000	1.3	3.3E-08	125	0.3	no APT
22	10	non-irr.	–	8 570	550 000	<0.1	–	105	0.2	FE only
23	10	non-irr.	–	8 540	548 000	0.7	3.2E-08	210	0.2	no IER
				8 570	550 000	0.9	4.3E-08	240	0.4	APT only
24	10	non-irr.	–	15 620	1 003 000	29.8	8.0E-07	240	0.5	
				8 570	550 000	<0.1	–	80	0.5	IER only
25	10	non-irr.	–	8 460	543 000	24.5	1.2E-06	240	0.5	
				8 570	550 000	20.3	9.9E-07	270	0.6	no FE
26	10	3/2001	144	490	31 400	561.9	4.7E-04	540	2.2	
27	10	3/2001	144	120	7 700	218.3	7.4E-04	400	1.4	
28	10	3/2001	144	490	31 400	671.8	5.6E-04	660	2.4	5 mm anter.
29	10	3/2001	145	8 570	550 000	26.5	6.3E-07	115	0.3	no APT
				490	31 400	444.0	3.7E-04	620	2.1	APT only
30	10	3/2001	145	8 645	555 000	10.0	2.4E-07	80	0.3	no APT
				490	31 400	576.8	4.8E-04	580	2.4	no FE

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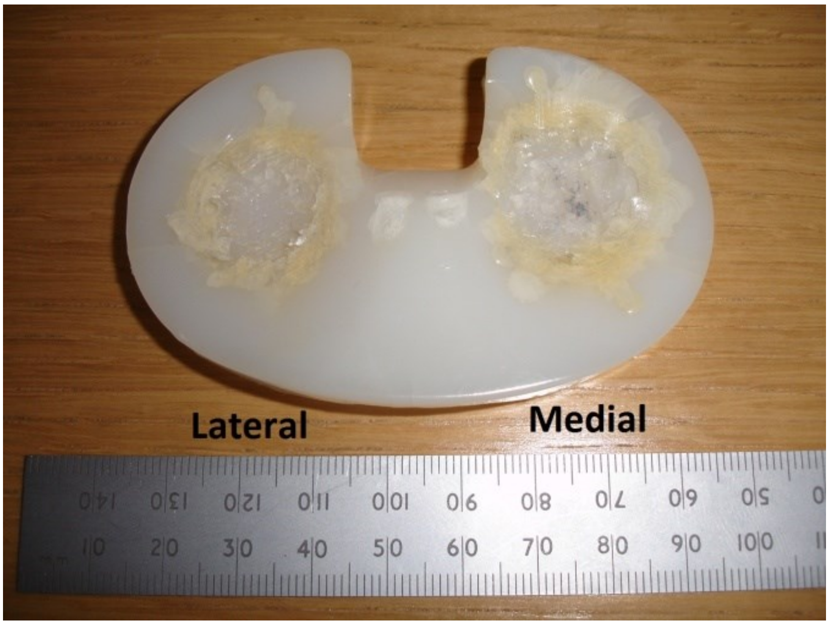


Figure 1. UHMWPE tibial component of prosthetic knee, removed from patient after 20 years of service, showing delamination damage.

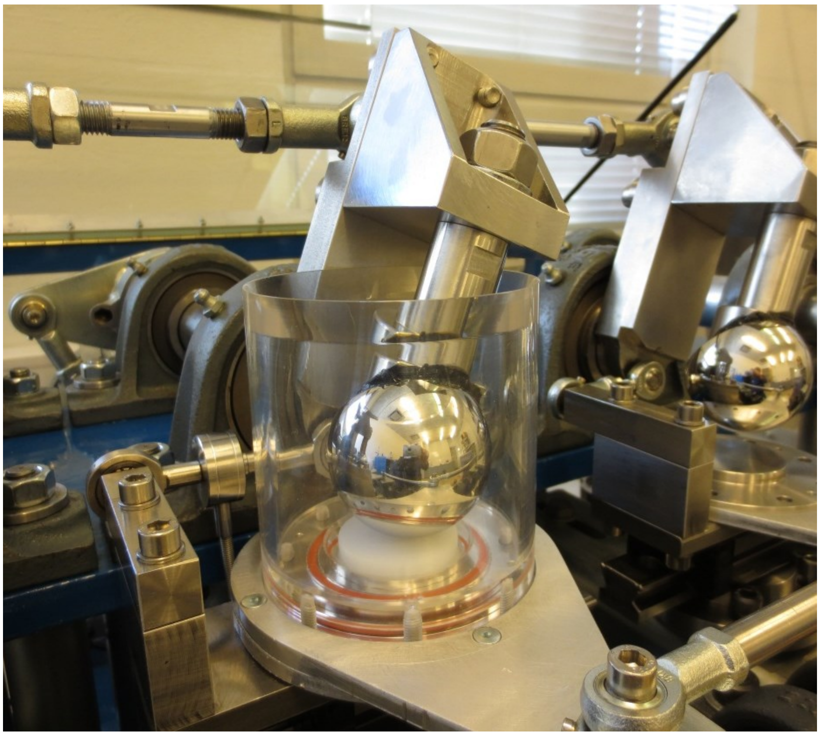


Figure 2. Close-up of five-station, three-axis BOF (ball-on-flat) knee wear simulator. Note load cell for measurement of APT (anterior-posterior translation) force, and clamping of UHMWPE test disk by acrylic lubricant chamber.

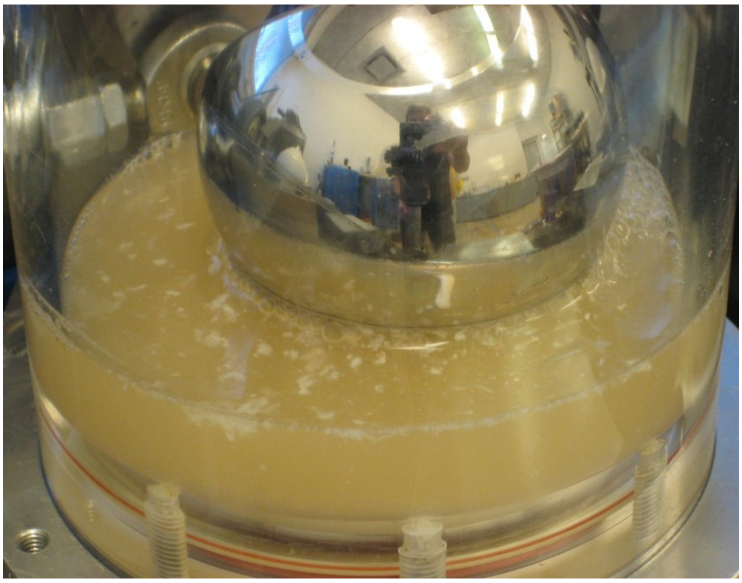


Figure 3. Polyethylene flakes floating on serum lubricant indicating delamination damage.

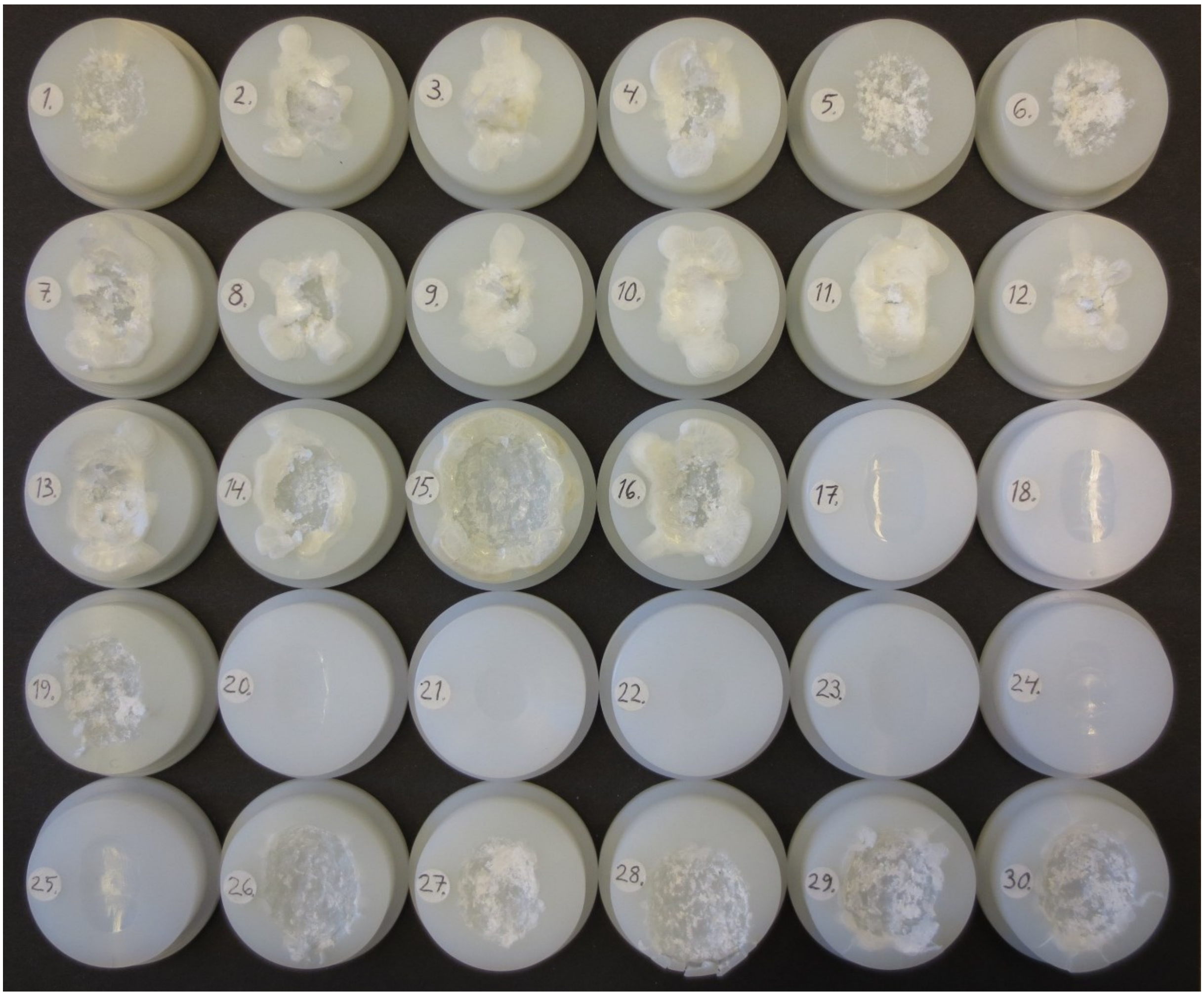


Figure 4. Shelf aged (discolored and delaminated) and reference UHMWPE disks after tests.

Figure 5. Cross-section chip from unused UHMWPE disk gamma-air-sterilized 3/2001 and shelf aged for 11 years showing subsurface white band caused by oxidative embrittlement.

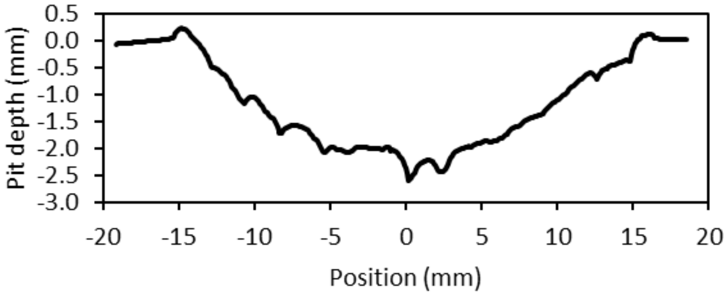
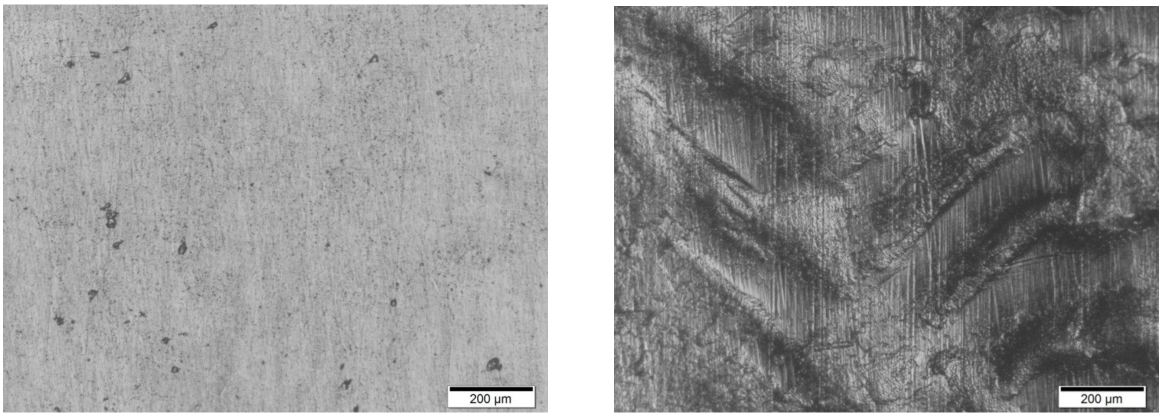
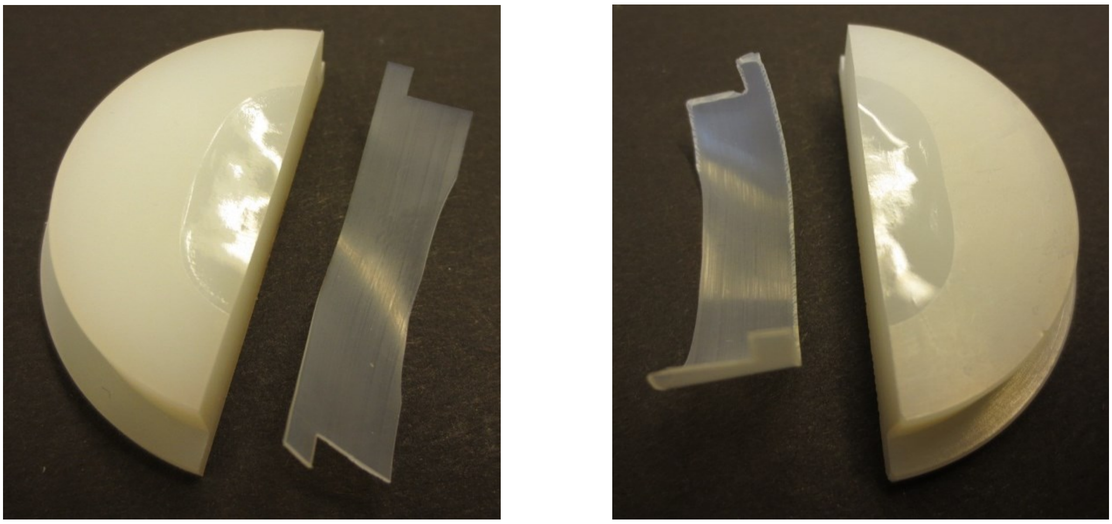


Figure 6. Profile of wear pit of disk 26 in anterior-posterior direction through center of pit measured with coordinate measuring machine (tip diameter 1.5 mm).



(A) (B)

Figure 7. Optical micrograph from bearing surface of (A) non-irradiated disk 17 after three-axis sliding (FE+APT+IER) showing burnishing, and (B) non-irradiated disk 25 showing undulations due to absence of FE. Anterior-posterior direction is top-down.



(A) (B)

Figure 8. Sectioned UHMWPE disks and their cross-section chips after gamma-air-sterilization, accelerated aging, and 5 million cycles (1 300 hours) in BOF simulator [7], (A) accelerated aging according to ASTM F2003-02, and (B) accelerated aging in air convection oven for 2 weeks at 100 ºC. There is no delamination in either, but burnished wear mark is similar to that of non-irradiated disks. There is no subsurface white band in cross-section chips, but surface oxidation can be seen in (B).

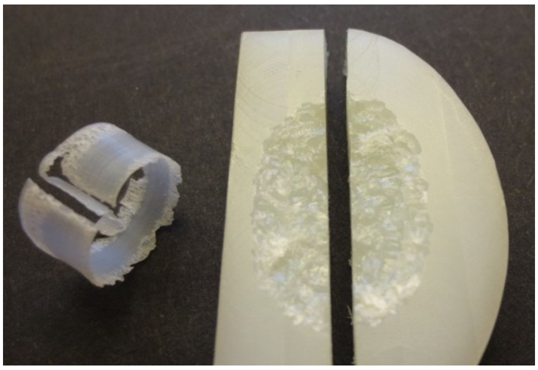


Figure 9. Sectioned specimen of Townley UHMWPE tibial component and cross-section chip. Component was gamma-air-sterilized, shelf aged for 10 years, and run in BOF simulator for 500 cycles (8 minutes) [7]. Layer on top of white band milled off before test. Note sharp edge of wear pit. Wear factor was 1.0×10^{-2} mm^3/Nm.